Complete Summary

GUIDELINE TITLE

A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States. Recommendations of the Advisory Committee on Immunization Practices (ACIP) part II: immunization of adults.

BIBLIOGRAPHIC SOURCE(S)

Mast EE, Weinbaum CM, Fiore AE, Alter MJ, Bell BP, Finelli L, Rodewald LE, Douglas JM Jr, Janssen RS, Ward JW, Advisory Committee on Immunization Practices (ACIP) Centers for Disease. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP) Part II: immunization of adults. MMWR Recomm Rep 2006 Dec 8;55(RR-16):1-33; quiz CE1-4. [3 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: CDC. Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination: recommendations of the Immunization Practices Advisory Committee (ACIP). MMWR 1991;40(No. RR-13).

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Hepatitis B virus (HBV) infection

GUIDELINE CATEGORY

Management
Prevention

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Hospitals
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To increase hepatitis B vaccination of adults at risk for hepatitis B virus infection

TARGET POPULATION

Adults at risk for hepatitis B virus infection

INTERVENTIONS AND PRACTICES CONSIDERED

1. Identification of persons with risk factors for hepatitis B virus (HBV) infection
2. Hepatitis B vaccination for all at-risk persons, including selection of appropriate vaccination schedule

MAJOR OUTCOMES CONSIDERED

- Rate of hepatitis B virus (HBV) vaccination among adults at risk for HBV infection
- Incidence of side effects and adverse events
- Interpretation of serologic test results for hepatitis B virus(HBV) infection
- Duration of immune memory
- Effectiveness of postexposure prophylaxis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In response to continuing low rates of hepatitis B vaccination among adults at risk for hepatitis B virus (HBV) infection, the Advisory Committee on Immunization Practices (ACIP's) Hepatitis Vaccines Work Group met multiple times during October 2004 to September 2005 to review previous guidelines and make recommendations for improving vaccination coverage in adults. The work group examined the progress made since 1991 in implementing the U.S. strategy to eliminate HBV transmission (e.g., vaccination coverage data and hepatitis B disease rates), surveillance data on missed opportunities for hepatitis B vaccination among adults with acute hepatitis B, and results of cost-effectiveness analyses. In addition, demonstration projects conducted in settings in which a high proportion of clients were at risk for HBV infection identified the components of successful adult hepatitis B vaccination programs and ongoing challenges to implementing adult hepatitis B vaccination.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

In January 2005, the proposed recommendations were posted online for public comment. In May 2005, Centers for Disease Control and Prevention convened a meeting of external consultants, including researchers, physicians, state and local public health professionals, immunization program directors, and directors of viral hepatitis, sexually transmitted disease, and human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) prevention programs, to obtain input into the draft recommendations and consider the feasibility of the recommended strategies. In October 2005, the revised recommendations were approved by Advisory Committee on Immunization Practices (ACIP).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

This report updates Advisory Committee on Immunization Practices (ACIP) recommendations published previously for hepatitis B vaccination of adults (*MMWR* 1991;40[RR-13]). The primary changes from previous recommendations are as follows:

- In settings in which a high proportion of persons are likely to be at risk for hepatitis B virus (HBV) infection (e.g., sexually transmitted disease/human immunodeficiency virus –STD/HIV] testing and treatment facilities, drug-abuse treatment and prevention settings, health-care settings targeting services to injection-drug users, health-care settings targeting services to men who have sex with men, and correctional facilities), ACIP recommends universal hepatitis B vaccination for all adults who have not completed the vaccine series.
- In primary care and specialty medical settings, ACIP recommends implementation of standing orders to identify adults recommended for hepatitis B vaccination and administer vaccination as part of routine services. To ensure vaccination of adults at risk for HBV infection who have not completed the vaccine series, ACIP recommends the following implementation strategies:
    - Provide information to all adults regarding the health benefits of hepatitis B vaccination, including risk factors for HBV infection and persons for whom vaccination is recommended.

- Help all adults assess their need for vaccination by obtaining a history that emphasizes risks for sexual transmission and percutaneous or mucosal exposure to blood.
- Vaccinate all adults who report risks for HBV infection.
- Vaccinate all adults requesting protection from HBV infection, without requiring them to acknowledge a specific risk factor.

Recommendations for Hepatitis B Vaccination of Adults

Hepatitis B vaccination is recommended for all unvaccinated adults at risk for HBV infection and for all adults requesting protection from HBV infection (see Box below titled "Adults Recommended to Receive Hepatitis B Vaccination"). Acknowledgment of a specific risk factor should not be a requirement for vaccination.

Box. Adults Recommended to Receive Hepatitis B Vaccination

Persons at risk for infection by sexual exposure

- Sex partners of hepatitis B surface antigen (HBsAg)-positive persons
- Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than one sex partner during the previous 6 months)
- Persons seeking evaluation or treatment for a sexually transmitted disease
- Men who have sex with men

Persons at risk for infection by percutaneous or mucosal exposure to blood

- Current or recent injection-drug users
- Household contacts of HBsAg-positive persons
- Residents and staff of facilities for developmentally disabled persons
- Health-care and public safety workers with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids
- Persons with end-stage renal disease, including predialysis, hemodialysis, peritoneal dialysis, and home dialysis patients

Others

- International travelers to regions with high or intermediate levels (HBsAg prevalence $\geq$2%) of endemic HBV infection (see Figure 4 and Box 2 in the original guideline document)
- Persons with chronic liver disease
- Persons with HIV infection
- All other persons seeking protection from HBV infection

Providers should select the vaccine schedule they consider necessary to achieve completion of the vaccine series (see Table 2 in the original guideline document and the Box below titled "Hepatitis B vaccine schedules for adults [aged >20 years]").

Box. Hepatitis B Vaccine Schedules for Adults (Aged ≥20 years)*

0, 1, and 6 months 0, 1, and 4 months 0, 2, and 4 months 0, 1, 2, and 12 months** *All schedules are applicable to single-antigen hepatitis B vaccines; Twinrix® (combined hepatitis A and hepatitis B vaccine) may be administered at 0, 1, and 6 months. ** A 4-dose schedule for Energix-B® is licensed for all age groups.

Public health programs and primary care providers should adopt strategies appropriate for the practice setting to ensure that all adults at risk for HBV infection are offered hepatitis B vaccine (see Box 6 in the original guideline document and "Description of the Implementation Strategy" field below).

See the following appendices in the original guideline document for further information:

- Appendix A: Immunization management issues
- Appendix B: Postexposure prophylaxis to prevent hepatitis B virus infection
- Appendix C: Identification and management of hepatitis B surface antigen (HBsAg)-positive persons

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Hepatitis B vaccination is the most effective measure to prevent hepatitis B virus infection and its consequences, including cirrhosis of the liver, liver cancer, liver failure, and death.

POTENTIAL HARMS

- The most frequently reported side effects in persons receiving hepatitis B vaccine are pain at the injection site (3 to 29%) and temperature of >99.9 degrees F (>37.7 degrees C) (1 to 6%). However, in placebo-controlled studies, these side effects were reported no more frequently among persons receiving hepatitis B vaccine than among persons receiving placebo.
- A causal association has been established between receipt of hepatitis B vaccine and anaphylaxis. On the basis of Vaccine Safety Datalink data, the estimated incidence of anaphylaxis among children and adolescents who received hepatitis B vaccine is one case per 1.1 million vaccine doses distributed (95% confidence interval = 0.1 to 3.9).
- Early postlicensure surveillance of adverse events suggested a possible association between Guillain-Barré syndrome (GBS) and receipt of the first dose of plasma-derived hepatitis B vaccine among U.S. adults. However, in a subsequent analysis of GBS cases reported to the Centers for Disease Control and Prevention, Food and Drug Administration, and vaccine manufacturers, among an estimated 2.5 million adults who received $\geq$1 dose of recombinant hepatitis B vaccine during 1986 to 1990, the rate of GBS that occurred after hepatitis B vaccination did not exceed the background rate among unvaccinated persons.
- One retrospective case-control study reported an association between hepatitis B vaccine and multiple sclerosis (MS) among adults. However, multiple studies have demonstrated no such association. Reviews by scientific panels have favored rejection of a causal association between hepatitis B vaccination and MS.
- In rare instances, chronic illnesses have been reported after hepatitis B vaccination, including chronic fatigue syndrome, neurologic disorders (e.g., leukoencephalitis, optic neuritis, and transverse myelitis), rheumatoid arthritis, type 1 diabetes, and autoimmune disease. However, no evidence of a causal association between these conditions or other chronic illnesses and hepatitis B vaccine has been demonstrated.
- Reported episodes of alopecia (hair loss) after rechallenge with hepatitis B vaccine suggest that vaccination might, in rare cases, trigger episodes of alopecia. However, a population-based study determined no statistically significant association between alopecia and hepatitis B vaccine.

CONTRAINDICATIONS

CONTRAINDICATIONS

Hepatitis B vaccination is contraindicated for persons with a history of hypersensitivity to yeast or any vaccine component. Despite a theoretic risk for allergic reaction to vaccination in persons with allergy to *Saccharomyces cerevisiae* (baker's yeast), no evidence exists to document adverse reactions after vaccination of persons with a history of yeast allergy.

Persons with a history of serious adverse events (e.g., anaphylaxis) after receipt of hepatitis B vaccine should not receive additional doses. As with other vaccines, vaccination of persons with moderate or severe acute illness, with or without fever, should be deferred until illness resolves. Vaccination is not contraindicated in persons with a history of multiple sclerosis, Guillain-Barré syndrome, autoimmune disease (e.g., systemic lupus erythematosus or rheumatoid arthritis), or other chronic diseases.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

In settings in which a high proportion of persons have risk factors for hepatitis B virus (HBV) infection (see Box below titled 'Settings In Which Hepatitis B Vaccination Is Recommended for All Adults'):

- All adults should be assumed to be at risk for HBV infection and should be offered hepatitis B vaccination if they have not completed a licensed hepatitis B vaccine series.
- Health-care providers should implement standing orders to administer hepatitis B vaccine as part of routine services to adults who have not completed the vaccine series and make hepatitis B vaccination a standard component of evaluation and treatment for sexually transmitted diseases (STDs) and human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) (see Table 3 in the original guideline document).
- When feasible, hepatitis B vaccination should be offered in outreach and other settings in which services are provided to persons at risk for HBV infection (e.g., needle-exchange programs, HIV testing sites, HIV prevention programs, and homeless shelters).

Box Settings In Which Hepatitis B Vaccination Is Recommended for All Adults

- Sexually transmitted disease treatment facilities
- Human immunodeficiency virus testing and treatment facilities
- Facilities providing drug-abuse treatment and prevention services
- Health-care settings targeting services to injection-drug users
- Correctional facilities
- Health-care settings targeting services to men who have sex with men
- Chronic-hemodialysis facilities and end-stage renal disease programs
- Institutions and nonresidential day care facilities for developmentally disabled persons

In primary care and specialty medical settings (e.g., physician's offices, family planning clinics, community health centers, liver disease clinics, and travel clinics), providers should implement standing orders to identify adults recommended for hepatitis B vaccination and administer vaccination as part of routine services. To ensure vaccination of persons at risk for HBV infection, health-care providers should:

- Provide information to all adults regarding the health benefits of hepatitis B vaccination, including the risk factors for HBV infection and persons for whom vaccination is recommended.
- Help all adults assess their need for vaccination by obtaining a history that emphasizes risks for sexual transmission and percutaneous or mucosal exposure to blood.
- Administer hepatitis B vaccine to adults who report risk factors for HBV infection.

- Provide hepatitis B vaccine to all adults requesting protection from HBV infection without requiring acknowledgment of a specific risk factor.

Occupational health programs should:

- Identify all staff whose work-related activities involve exposure to blood or other potentially infectious body fluids in a health-care, laboratory, public safety, or institutional setting (including employees, students, contractors, attending clinicians, emergency medical technicians, paramedics, and volunteers).
- Provide education to staff to encourage vaccination.
- Implement active follow-up, with reminders to track completion of the vaccine series among persons receiving vaccination.
- Provide appropriate postvaccination testing (see Appendix A in the original guideline document).

Providers in all settings in which hepatitis B vaccine is provided should:

- Assess patients' needs for other vaccines recommended for adults (schedule available at http://www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm) and administer these vaccines at the same office visit at which hepatitis B vaccine is administered.
- Identify and vaccinate all susceptible household, sex, and needle-sharing contacts of HBsAg-positive persons, and provide HBsAg-positive persons with appropriate referrals for counseling and medical management (see Appendix C in the original guideline document)
- Provide culturally appropriate materials to educate adults about hepatitis B and the importance of vaccination (available at http://www.cdc.gov/ncidod/diseases/hepatitis/b/index.htm#materials).
- Offer vaccination in a way that is accessible, convenient, and flexible for patients.
- Be familiar with Advisory Committee on Immunization Practices (ACIP's) general recommendations on immunization, which provide technical guidance regarding common immunization concerns of health-care providers.
- Give persons who are eligible for vaccination a copy of the most current vaccine information statement for hepatitis B vaccine, as required by federal law (see Appendix A in the original guideline document, 'Hepatitis B Vaccine Dose and Administration')
- Institute methods to identify persons with a history of vaccination (see Appendix A in the original guideline document, 'Unknown or Uncertain Vaccination Status')
- Provide vaccinated persons with a personal record card documenting receipt of vaccination (available at http://www.immunize.org/guide/aov21_appb_record.pdf).
- Develop tracking and reminder systems to ensure completion of the vaccine series (descriptions of such systems are available at http://www.cdc.gov/vaccines/recs/immuniz-records.htm).
- Report adverse events to Vaccine Adverse Events Reporting System (VAERS) using report forms and assistance available from CDC at telephone 1-800-822-7967 or from VAERS at http://www.vaers.hhs.gov/.

- Be familiar with billing and reimbursement guidelines for hepatitis B vaccination (available at http://www.ama-assn.org/ama1/pub/upload/mm/36/ama_hep_coding_trifo.pdf).

Public health agencies and medical organizations should educate providers about the benefits of hepatitis B vaccination for their patients and methods to implement and support hepatitis B vaccination services in their settings and practices. Health departments and community-based organizations should increase awareness of the benefits of hepatitis B vaccination, particularly among persons at increased risk for HBV infection. Educational materials are available at http://www.cdc.gov/ncidod/diseases/hepatitis/index.htm.

Health departments are encouraged to implement adult immunization registries to track the receipt of hepatitis B vaccine in all settings in which adults are vaccinated. Information on immunization registries is available at http://www.cdc.gov/vaccines/recs/immuniz-records.htm.

Although hepatitis B vaccination programs aim to achieve the highest possible rate of vaccine series completion, concerns regarding completion of the hepatitis B vaccine series should not preclude initiation of hepatitis B vaccination. Each dose of vaccine confers some protection against HBV infection. Vaccine immunogenicity is not decreased by lengthened intradose intervals, and the second and third doses can be administered during subsequent health-care visits outside of the recommended vaccine schedule.

IMPLEMENTATION TOOLS

Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Mast EE, Weinbaum CM, Fiore AE, Alter MJ, Bell BP, Finelli L, Rodewald LE, Douglas JM Jr, Janssen RS, Ward JW, Advisory Committee on Immunization Practices (ACIP) Centers for Disease. A comprehensive immunization strategy to

eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP) Part II: immunization of adults. MMWR Recomm Rep 2006 Dec 8;55(RR-16):1-33; quiz CE1-4. [3 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 (revised 2006 Dec 8)

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: CDC. Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination: recommendations of the Immunization Practices Advisory Committee (ACIP). MMWR 1991;40(No. RR-13).

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

Continuing Education activity is available from the Centers for Disease Control and Prevention (CDC) Web site.

PATIENT RESOURCES

None available

NGC STATUS

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